

October 4, 1999

Attention: Docket No. 98D-0969
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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The American Association of Bovine Practitioners' Committee on Pharmaceutical and Biologic Issues looks forward to participating in the December and February meetings related to antimicrobial resistance in food producing animals.

We strongly feel that the existing degree of risk of antimicrobial resistance in humans due to antimicrobial use in animals should be determined. Without an assessment of the overall risk to people of antimicrobial use in animals, monitoring of effects of policies to reduce resistance in people with changes in antimicrobial use or availability for animals would be meaningless. A reduction in risk implies there is a value for risk.

Likewise, a value for risk is necessary to determine the cost of interventions intended to reduce risk. For example, if an intervention cost \$10,000 and it reduced the risk from an estimated 5 work days lost per case of sickness due to antimicrobial resistance caused by antimicrobial use in food animals to 4.75 work days per case, policy makers would have to decide if the \$40,000 per work day was a good public investment.

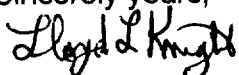
Similarly, thresholds should be determined based on calculations intended to show that above a certain level risk will change. If an antibiotic with an easily attainable MIC for a selected pathogen is found to have a small shift in MIC, the risk may remain constant.

In summary, without a beginning assessment of the risk of antimicrobial resistance in humans due to the use of antimicrobials in animals, the need to establish resistance thresholds, change preapproval studies, or the effect of any other policies to reduce risk would be difficult to measure.

We would encourage the participation in the future meetings of Drs. Kathy Ewert and Dave Dargatz. We feel that both have demonstrated knowledge and impartial judgment important to the success of the meetings.

The AABP very much looks forward to participation by member veterinarians and other experts at the Dec. 9-10 and Feb. 22-23 meetings.

Sincerely yours,



Lloyd L. Knight
Committee on Pharmaceutical and Biologic Issues

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